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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/676,358

10/02/2003

Karine Vidal

88265-6852

8288

29157 7590 06/09/2008  
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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

NOTIFICATION DATE

DELIVERY MODE

06/09/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/676,358	VIDAL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	CHIH-MIN KAM	1656	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-28 is/are pending in the application.
- 4a) Of the above claim(s) 12-16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17, 21 and 22 is/are allowed.
- 6) ☒ Claim(s) 18-20 and 23-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 12-28 are pending.

Applicants' amendment filed February 21, 2008 is acknowledged. Applicant's response has been fully considered. Claims 18-20, 23 and 25 and 19 have been amended. Claims 12-16 are non-elected inventions and withdrawn from consideration. Therefore, claims 17-28 are examined.

### **Withdrawn Claim Objections**

2. The previous objection to claim 26 is withdrawn in view of applicants' amendment to the claim 25 in the amendment filed February 21, 2008.

### **Withdrawn Claim Rejections - 35 USC § 102**

3. The previous rejection of claim 20 under 35 U.S.C. 102(b) as being anticipated by Simonet *et al.* (Cell 89, 309-319 (1997)), is withdrawn in view of applicants' amendment to the claims, and applicant's response at pages 6-7 in the amendment filed February 21, 2008.
4. The previous rejection of claims 18, 19, 23-25, 27 and 28 under 35 U.S.C. 102(b) as being anticipated by Goto *et al.* (EP 0816380), is withdrawn in view of applicants' amendment to the claims, and applicant's response at pages 6-7 in the amendment filed February 21, 2008.

### ***New Objection to the Specification***

5. The amendment filed February 21, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants indicate Figure 2 illustrates

Art Unit: 1656

osteoprotegerin including a glycosylation pattern giving rise to a polypeptide having a molecular weight between the claimed range (i.e., between 126 kDa and 130 kDa) as shown by the Western Blot analysis. However, it appears that Figure 2 shows the band having a molecular weight is approximately 130 kDa, it is not apparent that the band is actually between 126 kDa and 130 kDa.

Applicant is required to cancel the new matter in the reply to this Office Action.

***New Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 18-20 and 23-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 18-20 and 23-28 are directed to osteoprotegerin isolated from human or bovine milk or colostrums, wherein the osteoprotegerin includes a glycosylation pattern giving rise to a polypeptide having a molecular weight of between 126 kDa and 130 kDa; a food material, an enteral composition or a pharmaceutical composition comprising the osteoprotegerin; or a method of making a food material, an enteral composition or a pharmaceutical composition by adding the osteoprotegerin.

While the specification cites the OPG of the present invention, i.e. in a form obtainable from milk source, has a polypeptide sequence as identified by SEQ ID NO: 1 and exhibits sizes of about 80, 130 and 200 kDa, respectively, which differs from that (i.e., 55 kDa) obtained by recombinant means (see page 5, lines 8-10; page 12, lines 11-13); and the OPG of the present invention may be isolated from milk sources or prepared by recombinant means (page 8, lines 3-8), the specification does not show the OPG obtained from various milk fractions has a molecular weight of the band is actually between 126 kDa and 130 kDa (see the bands in Fig. 2). The specification only shows a band of molecular weight of about 130 kDa for various milk fractions and recombinant OPG, it is not apparent that the band is actually between 126 kDa and 130 kDa (Fig. 2). The lack of description for the osteoprotegerin isolated from human or bovine milk or colostrums having a glycosylation pattern giving rise to a polypeptide having a molecular weight of between 126 kDa and 130 kDa as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

### ***Conclusion***

7. Claims 18-20 and 23-28 are rejected; and it appears that claims 17, 21 and 22 are free of art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 1656

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

June 3, 2008